

Applicant : Victoria Beck et al.  
Serial No. : 09/800,431  
Filed : March 5, 2001  
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Attorney's Docket No.: 00231-088002 / USSN  
09/229,208; Beck

### REMARKS

Claims 1-20 and 30-39 are pending this application. Claims 21-29 have been cancelled without prejudice. Claims 1, 2, 6, 7, 9, 16-18, 20, 34, and 35 have been amended. The amendments to claims 1 and 16 are supported in the specification at, for example, page 6, lines 20-22. The amendments to claims 2, 6, 7, 9, 16-18, 20, 34, and 35 merely correct grammar or clarify existing claim language at the urging of the Examiner. New claims 37-39 are supported by the specification at, for example, page 13, line 28, to page 14, line 5. This amendment adds no new matter, and would require no further searching.

### Priority

The Examiner suggests that the specification be amended to reflect Applicants' claim of priority to United States Patent Application No. 09/229,208, filed on January 13, 1999, now United States Patent No. 6,197,746, which claims benefit of United States Provisional Patent Application No. 60/088,575. Applicants have amended the specification in accordance with the Examiner's suggestion.

### Objections

#### Specification

Examiner objects to the specification on the ground that "several pages within the specification have holes that make words illegible, and page 3 line 23 of specification is unclear wherein the words are not visible" (Office action at page 2). Applicants left a voicemail message for the Examiner on April 14, 2003, to clarify exactly what would be required to overcome this objection; however, applicants have not received a reply telephone call from Examiner Chism at the time of filing this response. So, applicants have included a high fidelity copy of the specification, as originally filed with the United States Patent & Trademark Office, with this reply, and hope that this copy of the specification will be sufficient to remove this ground for objection. In addition, applicants wish to clarify that page 3, line 23, reads as follows: "Prior to the discovery of the present invention, however,". Accordingly, applicants request that this ground for objection be withdrawn.

### Claims

The Examiner points out that the verb-forms "select", in claim 18, and "produces", in claim 20, do not accord with the grammar of the phrases in which they occur. Applicants' amendments accord with the Examiner's suggested corrections. Accordingly, applicants respectfully request that this ground for objection be withdrawn.

### Rejections

#### 35 U.S.C. §112, ¶1 (Enablement)

The Examiner has rejected claims 1-20 as allegedly lacking enablement. Applicants respectfully disagree, and maintain that all of these claims are fully enabled by the specification. However, for the sole purpose of moving prosecution forward, applicants have amended independent claim 1 (and dependent claim 16) to focus on autistic disorder and pervasive developmental disorder. As the Examiner helpfully points out, "the specification...[is] enabling for autism..." (Office action at page 3). Applicants wish the record to reflect that they have made the above amendments without prejudice to the enablement of the claims as filed. Furthermore, applicants reserve the right to pursue broader claims in a continuation application. Accordingly, applicants respectfully request that this ground for rejection be withdrawn.

The Examiner has rejected claim 11 as allegedly lacking enablement under 35 U.S.C. §112, ¶1. Applicants respectfully disagree. The specification provides instructions of more than adequate detail to allow one of ordinary skill in the art to employ acoustic waves to administer secretin to a patient: "For example, acoustic waves generated using ultrasound or a shockwave from a pulsed laser have been found to make the skin temporarily permeable. A few minutes of low-frequency ultrasound (sound greater in frequency than 20 kilohertz) creates tiny cavities through which the secretin (alone or combined with another transdermal carrier substance) can be diffused" (specification at page 13, line 28, to page 14, line 5). Accordingly, applicants respectfully request that this ground of rejection be withdrawn.

35 U.S.C. §112, ¶2 (Indefiniteness)

Claims 1-20 and 30-36 are rejected under 35 U.S.C. §112, ¶2 as allegedly being indefinite (Office action at pages 7-8). Since the Examiner only provides specific grounds for rejecting claims 1, 2, 4, 6-11, 16, 17, 19, 20, 30, 32, and 34-36, applicants have assumed that any defects to unenumerated claims stem from claims from which they depend.

Applicants note that amendments made to claim 1 for other reasons should now render moot this ground for rejection since “neurological and immunological disorders” is not longer recited in the pending claims.

Applicants appreciate the Examiner's observation that claim 2, as originally filed, accidentally depends from itself. Applicants have corrected this inadvertent mistake by amending claim 2 to depend from claim 1, as originally intended.

Applicants do not understand the Examiner's observation that “[claim] 30 [is] an improperly drawn claim as it depends from itself as claim 2” (Office action). Applicants assume that the Examiner inadvertently included claim 30 in this ground for objection; if not, applicants request clarification of the Examiner's objection to claim 30, as well as an opportunity to address any objection, once understood.

Applicants have also amended claim 2 to clarify that the “effective amount of secretin” recited therein refers to an “amount of secretin effective to stimulate secretion of the pancreatic juices”.

The Examiner rejects claims 4, 8, 32, and 36 as allegedly indefinite for employing the phrase “clinical unit” (or “CU”) (Office action at page 7). Applicants respectfully disagree that CU is indefinite. One of ordinary skill in the art would immediately understand that a CU is analogous to an “international unit” (or “IU”), which is a unit of biological material (*e.g.*, enzymes, hormones, vitamins) established by the International Conference for the Unification of Formulas. A CU is an IU for a therapeutic substance, such as secretin. Accordingly, applicants respectfully request that this ground for rejection be withdrawn.

The Examiner also rejects claims 6-9 and 34-35 as allegedly indefinite for employing the word “substance”. Applicants have followed the Examiner's advice (Office action at page 7),

and have amended claims 6, 7, 9, and 34-35 to remove reference to "substance". Accordingly, applicants respectfully request that this ground for rejection be withdrawn.

Applicants have amended claim 16 for reasons explained above. These amendments render moot the Examiner's rejection of this claim for indefiniteness. Accordingly, applicants respectfully request that this ground for rejection be withdrawn.

The Examiner rejects claim 17 as allegedly indefinite for reciting the phrase "sufficient to increase serotonin levels in the brain" (Office action at page 8). Applicants have amended claim 17 to clarify that the amount of secretin is "sufficient to increase serotonin levels in the brain of said patient to a level effective to stimulate secretion of the pancreatic juices". Accordingly, applicants respectfully request that this ground for rejection be withdrawn.

The Examiner rejects claim 19 and 20 as allegedly indefinite because they contain "no steps for stimulating the duodenum causing the secretion of effective amounts of secretin" and "it is not clear if this is a method beyond the use of secretin" (Office action at page 8). Applicants respectfully disagree that these claims are indefinite. In fact, the specification specifically points out that secretin is "secreted by the mucosa of the duodenum and upper jejunum when acid chyme enters the intestine" (specification at page 3, lines 13-15), thus offering an example of how to induce secretion of secretin in the patient's own intestinal tract. One of ordinary skill in the art would be aware of other such means. Accordingly, applicants assert that claims 19 and 20 are fully enabled by the specification, and they respectfully request that this ground for rejection be withdrawn.

Claims 6, 10-11, and 34 are rejected as allegedly indefinite for reciting "'portion of the skin' wherein it is not clear upon what area of the body the transdermal application is to be performed" (Office action at page 8). Applicants respectfully disagree. One of ordinary skill in the art would be well aware of how to apply secretin transdermally to a "portion of the skin" (or "a skin surface", as recited in claim 11). Typically, one of skill in the art would administer secretin through skin on the arm, though the abdomen, neck, leg, or other skin surfaces could also be successfully used. One of skill in the art would know that areas of thinner skin, hairless skin, and skin close to underlying blood vessels, would work well, while areas of thicker (or scarred) skin, hirsute skin, and skin distant from underlying blood vessels would work less well. Accordingly, applicants respectfully request that this ground of rejection be withdrawn.

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### Nonstatutory Obviousness-Type Double Patenting

Claims 1-4, 7, 30-32, and 35 are rejected under the judicially created doctrine of nonstatutory double patenting as being allegedly unpatentable over claims 1, 3, and 9 of United States Patent No. 6,020,310 (Office Action at page 9). Similarly, claims 1-2, 5-10, 17, 30, and 35-36 are rejected over claims 1-2, 5-10, 17, 30, and 33-36 of United States Patent No. 6,197,746 (Office action at page 9). The Office action states that “[a] timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application” (Office action at page 8). Although applicants do not agree with the Examiner’s conclusion, in the interests of moving this application towards allowance, applicants submit herewith a terminal disclaimer in compliance with 37 CFR 1.321(c), along with copies of documents demonstrating applicants’ chain of title. For this reason, applicants respectfully request that this rejection be withdrawn.

### 35 U.S.C. §102(a) (Novelty)

Claims 1-4 and 30-32 are rejected under 35 U.S.C. §102(a) as allegedly anticipated by Horvath *et al.* (*Journal of the Association for Academic Minority Physicians* 9(1):9-15, 1998) (Office action at page 102-103). However, applicants claim priority from United States Patent Application No. 09/080,631, filed May 19, 1998, which, in turn, claims priority from United States Provisional Patent Application No. 60/047,049, filed May 19, 1997. Applicants have clarified this implicit priority claim by amending the specification to recite it explicitly. Because Horvath *et al.* was published after the earliest priority date (that is, May 19, 1997), it cannot anticipate claims 1-4 or 30-32.

Accordingly, applicants respectfully request that this ground for rejection with withdrawn. In addition, applicants request that the official filing receipt be updated to reflect all clarifications in applicants’ claims to priority.